

<sup>1</sup> FORM COMPLE	TED BY			<sup>2</sup> DATE	
(Name and Desig	gnation)				
<sup>3</sup> NAME OF THE COMPANY/ ORGANISATION				<sup>4</sup> CONTACT DETAILS	
	name if applicable)				
<sup>5</sup> REGISTERED AD				<sup>6</sup> SPECIFIC PRODUCTS	
(Address on the	bid document)			TO BE SUPPLIED	
	/			(attach list)	
DISTRIBUTION	-				
MANUFACTURI	NG SITE ADDRESS				
<sup>7</sup> NAME AND	RP NAME			EMAIL	
CONTACT				CONTACT NUMBER	
DETAILS FOR	QP NAME			EMAIL	
RECALL				CONTACT NUMBER	
PURPOSES	RECALL CONTACT NAME			EMAIL	
		X YES		CONTACT NUMBER	
	<sup>8</sup> CONFIRMATION OF WHOLESALE DEALERS		WDA(H) OR EQUIVALENT		LAST INSPECTION
	l or equivalent, and GDP	🗆 NO	AUTHORISATION NUMBER		DATE AS PER GDP
CERTIFICATE (if applicable)		🗆 N/A			CERTIFICATE AND
					EXPIRY DATE (IF
Attach copy		□ YES			APPLICABLE)
	<sup>9</sup> CONFIRMATION OF GMP CERTIFICATE or		GMP CERTIFICATE OR		LAST INSPECTION
equivalent					DATE/ CERTIFICATE
		□ N/A	AUTHORISATION NUMBER		EXPIRY DATE
Attach copy	N OF CONTROLLED DRUGS	□ YES	CD LICENCE OR		LAST INSPECTION
<sup>10</sup> CONFIRMATION OF CONTROLLED DRUGS LICENCE or equivalent			EQUIVALENT		DATE/ CERTIFICATE
			AUTHORISATION NUMBER		EXPIRY DATE
Attach copy					
	F PRODUCTS APPROVED TO BE				
	ding to licence(s))				
(4000)		1			



<sup>12</sup> AUTHORISATION TO HANDLE MEDICINAL	
PRODUCTS WITH ADDITIONAL REQUIREMENTS	
(according to licence(s))	
(Specify type of additional requirements)	
<sup>13</sup> APPROVED ACTIVITIES ON LICENCE(S)	
(Specify type of activity)	
<sup>14</sup> NAME AND CONTACT DETAILS OF NATIONAL/	
LOCAL REGULATORY AUTHORITY for all licences	
<sup>15</sup> LANGUAGE(S) ON LICENCE(S)	
If no English version then a certified translation	
is required.	
<sup>16</sup> EVIDENCE OF REGISTER(S) OF APPROVED	
WDA/GMP/CD LICENCE	
(National/ Local Regulatory Authority)	
<sup>17</sup> LIST ADDITIONAL LICENCES SUPPLIED	
In addition to the above e.g. GDP/ WHO/ ISO/	
Import/ Export/ Transport etc)	
<sup>18</sup> IF PROVIDING TRANSPORTATION TO THE END	
USER, PLEASE PROVIDE DETAILS OF either IN-	
HOUSE PROVISION or APPROVED THIRD PARTY	
providers, for each CATEGORY OF PRODUCT to	
be supplied (CDs, cold chain, ambient, other)	
a) Are the temperature-controlled vehicles MAINTAINED in	YES NO - PLEASE SPECIFY:
accordance with the manufacturer's recommendations, validated and calibrated?	
b) NAME, ADDRESS, and DATE OF LAST APPROVAL of	
transportation provider:	
<ul> <li>OUT OF HOURS/Emergency contact details in respect of transportation:</li> </ul>	
d) Do you have a DISASTER PLAN in place for BREAKDOWNS	YES NO - PLEASE SPECIFY:
or ACCIDENTS?	
<ul> <li>e) Do you have QUALITY TECHNICAL AGREEMENTS or written contracts in place with your transportation</li> </ul>	YES NO - PLEASE SPECIFY:
provider/s?	
<ul> <li>f) Do you have your own TRANSIT HUBS, if so, please specify the locations and if they hold a licence or</li> </ul>	YES NO - PLEASE SPECIFY:
authorisation?	



# FOR COMPLETION BY CROWN AGENTS:

SUPPLIER

OTHER(provide details)

NAME OF CA employee responsible for this supplier/client/customer/other:

Link to GDP Sharepoint folder:

<sup>19</sup> PROOF ACQUIRED AND UPLOADED TO GDP SHAREPOINT (Tick all applicable)	COMMENTS
COPY OF ORIGINAL WDA CERTIFICATE/EQUIVALENT	
COPY OF GDP CERTIFICATE (if appropriate)	
COPY OF ORIGINAL GMP CERTIFICATE/EQUIVALENT	
COPY OF ORIGINAL CD CERTIFICATE/EQUIVALENT	
VALIDATION OF LICENCES - RELEVANT PAGE FROM MHRA/EUDRA GMDP/NATIONAL/LOCAL REGULATORY REGISTER (link or screenshot) OR LETTER FROM CERTIFICATE ISSUING AUTHORITY	
EUDRA GMDP NON-COMPLIANCE REPORTS (if in EAA)	
CERTIFIED LICENCE TRANSLATION (if not in English)	
DUE DILIGENCE AUTHORISATION (EDD + FDD)	
LIST OTHER CHECKS/RELEVANT DOCUMENTS (screenshots of Google maps, website checks, blacklists etc)	



		<sup>20</sup> APPROVALS	
CHECKS COMPLETED BY GDP & CM		SIGNATURE	DATE
APPROVED BY SHCM&RP/RP		SIGNATURE	DATE
APPROVED BY THE AO in the case of CDs (where applicable)		SIGNATURE	DATE
COMMENTS AND DATE OF NEXT REVIEW	APPROVED C REJECTED C		
	DATE for NEXT REVIEW:		



# Form Completion Guidance:

1	"CHECKS COMPLETED BY"
	The individual completing the form
2	"DATE"
	Date of completing this form
3	"NAME OF THE COMPANY/ ORGANISATION"
5	Specify name of company/ organisation to which the bona fides relate i.e. the company with whom a contract will be signed
	Speciry name of company. Organisation to which the bona nees relate i.e. the company with whom a contract will be signed
4	"CONTACT DETAILS"
4	Provide contact details including email, telephone number and website address of the company/ organisation to which the bona fides relate
	Fronde contact details including email, telephone number and website address of the company, organisation to which the bona rides relate
_	
5	"ADDRESS"
	Official address of the company/ organisation with whom a contract will/could be concluded and also the address of the distribution site (which could be a third party site – for which a licence would need to be
	provided) or the manufacturing site (if form relates to a manufacturer and a GMP licence)
6	"SPECIFIC PRODUCTS TO BE SUPPLIED"
	Attach list of medicines showing product category, from bid documents, to include name, dosage and product license/registration details of each product. Attach as an appendix if necessary.
7	"NAME AND CONTACT DETAILS FOR RECALL PURPOSES"
	"RP NAME" "EMAIL" "CONTACT NUMBER"
	Name, Email and Contact Number of the Responsible Person (RP) for the company/ organisation to which the bona fides relate, if a supplier.
	"QP NAME" "EMAIL" "CONTACT NUMBER"
	Name, Email and Contact Number of the Qualified Person (QP) for the company/ organisation to which the bona fides relate.
	"RECALL CONTACT NAME" "EMAIL" "CONTACT NUMBER"
	Name, Email and Contact Number of the Recall Contact for the company/ organisation to which the bona fides relate.
8	"CONFIRMATION OF WHOLESALE DEALERS AUTHORISATION OR EQUIVALENT" WDA(H) OR EQUIVALENT AUTHORISATION NUMBER
0	"LAST INSPECTION DATE AS PER GDP CERTIFICATE AND EXPIRY DATE (IF APPLICABLE)"
	Add the authorisation/licence reference number and the inspection and expire dates (if applicable) of any GDP certificate

Add the authorisation/licence reference number and the inspection and expiry dates (if applicable) of any GDP certificate .

9 "CONFIRMATION OF GMP COMPLIANCE CERTIFICATE OR EQUIVALENT" "GMP CERTIFICATE OR EQUIVALENT AUTHORISATION NUMBER" "LAST INSPECTION DATE/ CERTIFICATE EXPIRY DATE" Add the certificate reference number and issue/expiry dates (if applicable)

"CONFIRMATION OF CONTROLLED DRUGS LICENCE OR EQUIVALENT" "CD LICENCE OR EQUIVALENT AUTHORISATION NUMBER" "LAST INSPECTION DATE/ CERTIFICATE EXPIRY DATE" Add the certificate reference number and issue/expiry dates (if applicable)

11 "CATEGORIES OF PRODUCTS APPROVED TO BE HANDLED"

10

Add the product categories approved to be handled for example P med, POM, GSL, THR's etc.



12 "AUTHORISATION TO HANDLE MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS"

Add the type of additional requirements authorised for example narcotic or psychotropic products, medicinal gases, cold chain etc.

#### 13 "APPROVED ACTIVITIES"

Add the activities which are licenced for example, manufacture, supply, procurement, holding, export etc.

### "NAME AND CONTACT DETAILS OF NATIONAL/ LOCAL REGULATORY AUTHORITY"

State the name of the local regulator which issued the licence/certificate(s) as well as all contact details for the applicable regulatory authority.

### 15 "LANGUAGE ON LICENCES"

14

State the language(s) of the licences and if English is not one of them, then provide a certified translation into English. .

16	"EVIDENCE OF REGISTER OF APPROVED WDA/GMP/CD LICENCES"
	Provide evidence that licences supplied are currently on the appropriate local regulatory authority register (link, screenshot, letter etc)

17	"LIST ADDITIONAL LICENCES SUPPLIED" Document all licences supplied with this form to Crown Agents, which may include WHO/ISO/EXPORT/IMPORT/CDs/TRANSPORT etc.
18	"TRANSPORTATION"
	Only to be completed by a Supplier, if providing Transportation services.



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 "PROOF ACQUIRED AND UPLOADED TO GDP SHAREPOINT"

 A folder specific to the supplier/client on the GDP SharePoint site: documents/bona fide checks/clients and suppliers/ should be created, unless a folder already exists, where all the following supporting documentation including the completed version of this form should be saved.

 "COPY OF ORIGINAL WDA CERTIFICATE/EQUIVALENT"
 "COPY OF ORIGINAL GMP CERTIFICATE/EQUIVALENT"

 "COPY OF ORIGINAL GMP CERTIFICATE/EQUIVALENT"
 "COPY OF CONTROLLED DRUGS CERTIFICATE/EQUIVALENT"

 "RELEVANT PAGE FROM MHRA/EUDRA GMDP/NATIONAL/LOCAL REGULATORY REGISTER OF APPROVED WHOLESALE DEALERS AND/OR MANUFACTURERS (WDA/GMP/CD CERTIFICATE)

 "EUDRA GMDP NON-COMPLIANCE REPORT" IF EAA BASED
 "CERTIFIED LICENCE TRANSLATION" (if appropriate)

 "ETHICAL DUE DILIGENCE AUTHORISATION"
 "If appropriate)

 "ETHICAL DUE CHCKS/RELEVANT DOCUMENTS "
 [Google maps, contact details, website domain names, etc.]

 Website registration details: <a href="https://www.virustotal.com/">https://www.virustotal.com/</a>

 Check if 'blacklisted': <a href="https://www.virustotal.com/">https://www.virustotal.com/</a>

## 20 "APPROVALS"

This section needs to be completed and signed off by all relevant Crown Agents parties once bona fide checks have been completed. Only if the products to be supplied include CDs then the Accountable Officer for CA's Home Office licence, also needs to sign.